



Food and Drug Administration
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January 27, 2015

Romedex International SRL
Sorin Grunwald, PhD.
Managing Director
625 Clayton Street
San Francisco, CA 94117

Re: K141634

Trade/Device Name: Nautilus Delta™
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long- term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: December 15, 2015
Received: December 17, 2015

Dear Dr. Grunwald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141634

Device Name
Nautilus Delta

Indications for Use (Describe)

Nautilus Delta is indicated for navigation and positioning of central venous access devices (CVADs) of at least 3 Fr in size. Nautilus Delta provides real-time catheter tip location information by using the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for CVAD tip placement confirmation. In adult patients and in adolescents (greater than 12 through 21 years of age), Nautilus Delta can be used with CVADs such as peripherally inserted central catheters (PICCs), central venous catheters (CVCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), Nautilus Delta can be used with PICCs and with centrally inserted central catheters (CICCs); in infants (greater than 1 month to 2 years of age) and in neonates (from birth to 1 month of age), Nautilus Delta can be used with CICCs. In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use. Limiting but not contraindicated situations for this method are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Proprietary Name: Nautilus Delta™ also known as Handy Nautilus™

Device Trade Name: Nautilus Delta™

Applicant Name: Romedex International SRL

Applicant Address: 74 Fundeni Str., 022325, Bucharest, Romania
+40.21.255.0385, info@romedex.com, www.romedex.com

Contact person: Sorin Grunwald PhD, 625 Clayton Str., San Francisco, CA 94117
sorin@romedex.com, Tel: +1.650.209.4838, Fax: +1.650.636.9666

Date of Preparation: June 16, 2014

Product Classification: Class II, 21 CFR §880.5970
LJS - Accessory to Percutaneous, Implanted, Long-Term
Intravascular Catheters

Classification Panel: General Hospital

Predicate devices: Epidural Catheter Connector (K973371)
Sherlock 3CG Tip Confirmation System (K113808)

Device Description: The Nautilus Delta™ system consists of the following elements: single use sterile ECG extension cable (also known as Nautilus Electrical Adaptor also known as NautilusE), non-sterile ECG cable, patient module (ECG data acquisition and processing and integrated remote control), and mobile medical application running on any mobile platform which complies with the minimum requirements. Nautilus Delta™ provides real-time catheter tip location information by using the patient's cardiac electrical activity (ECG). This information can be used to position any central venous access devices (CVADs) at or around the cavo-atrial junction (CAJ). Nautilus Delta supports navigation of central venous catheters from the vascular access point towards the CAJ by computing and displaying a navigation signal. Nautilus Delta also displays on its graphical user interface the surface (skin) ECG signal, a marker identifying the R-peak, and the patient's heart rate. In order to obtain intravascular ECG information at the tip (distal end) of a catheter, a stylet or a guidewire inserted in the catheter can be connected to Nautilus Delta patient module via the sterile Nautilus Delta ECG extension cable. Nautilus Delta and NautilusE do not have any direct or indirect contact with the patient.

Intended Use:	The intended use of Nautilus Delta™ is to support navigation and tip positioning of central venous access devices. Nautilus Delta™ can be used as an alternative method to fluoroscopy and chest X-ray for central venous catheter tip placement confirmation.
Indications for Use:	<p>Nautilus Delta is indicated for navigation and positioning of central venous access devices (CVADs) of at least 3 Fr in size. Nautilus Delta provides real-time catheter tip location information by using the patient's cardiac electrical activity and is indicated for use as an alternative method to chest X-ray and fluoroscopy for CVAD tip placement confirmation.</p> <p>In adult patients and in adolescents (greater than 12 through 21 years of age), Nautilus Delta can be used with CVADs such as peripherally inserted central catheters (PICCs), central venous catheters (CVCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), Nautilus Delta can be used with PICCs and with centrally inserted central catheters (CICCs); in infants (greater than 1 month to 2 years of age) and in neonates (from birth to 1 month of age), Nautilus Delta can be used with CICCs. In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use.</p> <p>Limiting but not contraindicated situations for this method are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.</p>
Summary of Technological Characteristics compared to Predicate Devices:	<p>Nautilus Delta has features, materials and technological characteristics which are similar to the ones of the predicate devices. The most notable differences are:</p> <ul style="list-style-type: none"> a) Nautilus Delta uses wireless technology (Bluetooth) instead of an USB cable for the ECG data transmission between the Patient and the Operator modules. b) Nautilus Delta uses a mobile platform instead of a netbook PC. c) Nautilus Delta provides a Bluetooth remote control integrated in the Patient Module instead of a standalone Bluetooth remote control. d) Nautilus Delta provides an additional optional navigation signal to support catheter tip navigation from the vascular access point towards the cavo-atrial junction. e) Nautilus Delta displays the patient's heart rate and markers to identify the R-peak of the QRS complex of the ECG waveform.

**Summary of
Performance Testing:**

Romedex has performed extensive testing in order to demonstrate that the new characteristics do not affect safety and effectiveness when compared to the predicate devices and to demonstrate compliance with the following standards: ES60601-1, IEC 60601-1-2, IEC 60601-2-27, IEC 62304, IEC 62366, ISO 11737-1, ISO 11135-1, ISO 11135-2, EN 55022, and EN 300328.

**Summary of
Clinical Data:**

Since obtaining the CE mark, Nautilus Delta also known as Handy Nautilus was successfully used in Europe in hundreds of patients in several hospitals in several countries by many different users of different backgrounds and experience levels. No adverse events were reported. Side-by-side comparisons with legally marketed similar devices, including the predicate devices, were performed in clinical settings to demonstrated substantial equivalence of Nautilus Delta with the predicate devices.

**Summary of
Substantial Equivalence:**

Based on the analysis of the indications for use, intended use, technological characteristics, performance tests, and post-market clinical experience, Romedex International has concluded that the new characteristics of the subject device do not affect the safety or effectiveness of the subject device as compared to the predicate devices. Romedex International considers that the new device Nautilus Delta is substantially equivalent to the predicate devices K973371 and K113808.